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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,412	07/11/2001	Shohei Koide	109.050US1	8219

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/903,412

Applicant(s)

KOIDE, SHOHEI

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8 and species, Asn for Asp at position 7 in Paper No. 8 is acknowledged. The traversal is on the ground(s) that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it arguably may include claims to distinct or independent inventions. This is not found persuasive because to examine the 50 different and distinct invention would indeed imposed an undue burden of examination. The search for each groups containing distinct inventions entails searching all literatures and foreign patents. These searches are not co-extensive with U.S. Patents searches. A prior art reference anticipating one invention would not render the other inventions obvious.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Status of Claims

Claims 1-8 are under examination.

Claims 9-50 are withdrawn from consideration as being drawn to non-elected invention, as stated above.

Priority

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed provisional application, specific reference to the provisional application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Information Disclosure Statement

The listing of references in the specification, pages 78-89 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into

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the specification but must be submitted in a separate paper."

Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Koide (WO 98/56915) or Lipovsek (WO 00/34784).

Koide discloses at page 6, lines 12-26 a fibronectin (Fn3) polypeptide monobody comprising a plurality of Fn3 beta-strand domain sequences that are linked to a plurality of loop region sequences. One or more of the monobody loop region sequences of the Fn3 polypeptide vary by deletion, insertion or replacement of at least two amino acids from the corresponding loop region sequences in wild-type Fn3. One or more of the loop regions of the monobody comprise amino acid residues: i) from 15 to 16 inclusive in an AB loop; ii) from 22 to 30 inclusive in a BC

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loop; iii) from 39 to 45 inclusive in a CD loop; iv) from 51 to 55 inclusive in a DE loop; v) from 60 to 66 inclusive in an EF loop; and vi) from 76 to 87 inclusive in an FG loop. Koide discloses that 17 Fn3 domains are present just in human fibronectin that provides important information on conserved residues which are often important for the stability and folding. Large variations are seen in the BC and FG loops, Example XVII, page 51. See further the Examples, specifically the Tables. The tables show the different amino acid substitutions for the integrin binding motif, RGD. Accordingly, the broadly claimed Fn3 with amino acid mutations is fully met by Koide disclosing a Fn3 mutated at different positions of the Fn3 loops.

Lipovsek basically discloses the same Fn3 mutant as Koide. Lipovsek at page 17, lines 12-15, discloses substitutes of the Fn3 at other positions such as positions 1-9. Accordingly, Lipovsek fully meets the claimed limitation of Fn3 having mutations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Koide(I) or Lipovsek in view of Blaschuk (U.S. 6,391,855).

Either Koide or Lipovsek discloses or at least suggests substituting amino acid residues Asp at positions 7 and 9 (Lipovsek) or 23 (Koide) of the Fn3 molecule with a library containing different amino acids. The residues in the library can include Glu or Lys for Asp. These modifications by substitutions (e.g., side chain modifications) are conservative substitutions, as taught by Blaschuk at col. 8, lines 53-66. Blaschuk discloses that a "conservative substitution" is one in which an amino acid is substituted for another amino acid that has similar properties, such that one skilled in the art of peptide chemistry would expect the secondary structure and hydrophobic nature of the polypeptide to be substantially unchanged. Amino acid substitutions may generally be made on the basis of similarity in polarity, charge, solubility, hydrophobicity, hydrophilicity and/or the amphipathic nature of the residues. For example, negatively charged amino acids

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include aspartic acid and glutamic acid; positively charged amino acids include lysine and arginine. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the Asp residue at positions 7 or 9 in the Fn3 molecule of either Koide or Lipovsek with another acidic residue, Glu or with another charged amino acids as Lys as taught by Blaschuk. This substitution is taught by Blaschuk are conservative substitutions. The secondary structure and hydrophobic nature of the polypeptide or its solubility are substantially unchanged or if not stabilize. One having ordinary skill in the art would have reasonably expected that the result obtained from one member of a family could be similarly obtained for the other member.

No claim is allowed.

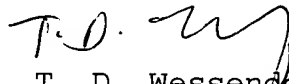
Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be

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reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
April 5, 2003